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Patent Application
Docket No. PC11032A

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By Kelly A. Smith
(Signature of person mailing)
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Mathew Merrill Hayward *et al.*

Serial No.: 09/872,731
Filed: June 1, 2001

Group Art Unit: 1624
Examiner: LIU, HONG

For: HYGROMYCIN A DERIVATIVES

RESPONSE

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is being filed in response to the Office Action mailed on May 31, 2002. A request for a three month extension of time, and the authorization for payment of the appropriate fee, is separately enclosed herewith.

Remarks

Claims 1-8 are pending in the present application.

The Examiner has rejected pending Claims 1-8 as being non-enabling under 35 USC 112, first paragraph. The Examiner has also rejected pending Claims 1 and 3 as being indefinite under 35 USC 112, second paragraph. The Examiner has further rejected pending Claims 1-8 as being obvious under 35 USC 103(a).

The Examiner's rejection of the pending Claims shall now be addressed in the order made by the Examiner.

Rejection of Claims 1-8 Under 35 USC 112, First Paragraph

Claims 1-8 are rejected under 35 USC §112, first paragraph, as not enabling the scope of the term "prodrug". The Examiner states that Applicants provide no guidance as to how the compounds are made more active *in vivo*. The Examiner also states that the choice of a prodrug will vary from drug to drug and that more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

Contrary to the Examiner's statement, the term "prodrug" is suitably enabled in the present application. Examples of suitable prodrugs, and methods for making such prodrugs, are described in the Specification from page 9, line 13, to page 10, line 5.

In addition, Applicants are not required to provide guidance on how compounds are made more active *in* vivo as there is no legal requirement that a novel prodrug of a novel compound must improve *in vivo* activity of the novel compound in order to be patentable as a prodrug.

Furthermore, to be enabling, Applicants' are not required to identify a "choice" prodrug, but rather, the application must enable one of ordinary skill to make suitable prodrugs of compounds of the present invention

without undue experimentation. Suitable prodrugs are those that are useful in that they will work to some degree. Suitable prodrugs are not limited to a "choice" prodrug as implied by the Examiner. Therefore, many suitable prodrugs of the present invention can be made and identified, based upon the disclosure in the present application, by one of skill in the art without undue experimentation.

Thus, pending Claims 1-8 are improperly rejected as being non-enabling.

Rejection of Claims 1 and 3 Under 35 USC 112, Second Paragraph

Claims 1 and 3 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants claim as the invention. Specifically, the Examiner stated that the use of the term "heterocyclic" in the definition of R is unclear to the array of heteroatoms as well as the nature of the ring members.

Contrary to the Examiner's statement, the term "heterocyclic" is generically described, with specific examples also cited, in the Specification on page 7, lines 11-34. Further, similar definitions for the term "heterocyclic" are routinely found to be not indefinite by the USPTO. For example, please see Column 15, line 55, to Column 16, line 31, of US Patent No. 6,245,745 which issued on June 12, 2001 wherein the same definition of "heterocyclic" is provided.

Thus, pending Claims 1 and 3 are improperly rejected as being indefinite.

Rejection of Claims 1-8 for Obviousness Under 35 U.S.C. §103(a)

Claims 1-8 are rejected under 35 USC 103(a) as being unpatentable over US Patent No. 6,245,745.

Contrary to the Examiner's statement, US 6,245,745 is not valid prior art for the claims in the present patent application in that US 6,245,745 does not constitute valid prior art under 35 U.S.C. Sections 102(a)-(g). More specifically, US 6,245,745 was not patented, and its teachings were not published, on the date of invention of the Applicants' invention. In fact, US 6,245,745 was not patented, and its teachings were not published, as of the US priority date of June 2, 2000.

Furthermore, the Applicants' application (USSN 09/872,731) and US 6,245,745 were, at the time the invention of USSN 09/872,731 was made, commonly owned by Pfizer Inc.

Thus, pending Claims 1-8 are improperly rejected as being obvious in view of US 6,245,745.

Conclusion

Based on the foregoing, Applicants respectfully submit that the Examiner's rejections, under 35 USC 112, first and second paragraphs, and under 35 USC 103(a), are improper. Therefore, Applicants respectfully request that the rejections of Claims 1-8 under 35 USC 112, first and second paragraphs, and under 35 USC 103(a) be withdrawn.

Applicants further request that a notice of allowance be issued for pending Claims 1-8.

Respectfully Submitted:

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